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Paper No. 122

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

DONALD G. WALLACE,
HUGH McMULLIN,
and
GEORGE CHU

Junior Party,¹

v.

WILLIAM G. HUBBARD

Senior Party.²

Patent Interference No. 103,570

FINAL HEARING: JUNE 26, 2001

Before CAROFF, HANLON, and LORIN, Administrative Patent Judges.

CAROFF, Administrative Patent Judge.

¹Patent 5,204,382, granted April 20, 1993, based on Application 07/920,412, filed July 27, 1992. Accorded the benefit of U.S. Application No. 07/843,646, filed February 28, 1992. Assignment to Cohesion Technologies, Inc.

²Application 08/159,071, filed November 29, 1993. Accorded the benefit of U.S. Application Nos. 07/833,874, filed February 11, 1992, and 07/999,411, filed January 21, 1993. Assignment to Bioform, Inc.

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PAT & TM OFFICE
BOARD OF PATENT APPEALS
AND INTERFERENCES

Interference No. 103,570

FINAL DECISION

This interference involves a patent of the junior party, Wallace et al. (Wallace), and an application of the senior party, Hubbard. According to the record before us, the Wallace patent is assigned to Cohesion Technologies, Inc. (Paper No. 104), and the Hubbard application is assigned to Bioform, Inc. (Paper No. 108).

The subject matter in issue relates to a method for augmenting tissue in a mammal by administration of a composition including a matrix of ceramic particles and a fluid carrier. This subject matter is more particularly defined by the sole count in issue, count 2, which reads as follows:

Count 2.

(a) [Wallace et al. claim 1]

[1.] A method for augmenting tissue in a living mammal, said method comprising subcutaneously injecting a composition including a ceramic matrix present in a pharmaceutically acceptable fluid carrier to a tissue site, wherein the ceramic matrix comprises particles having a size distribution in the range from 50 μm to 250 μm .

or

(b) [Hubbard claim 21]

[21.] A method for soft tissue augmentation comprising introducing at a desired site of a mammalian species in need of such soft tissue augmentation material comprising a matrix of rounded, substantially spherical, biocompatible, substantially non-resorbable, finely divided ceramic particles close to or in contact with each other, said

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particles having a size distribution in the range from 15 μm to 150 μm .

or

(c) [Hubbard claim 46]

[46:] A method for augmenting tissue in a living mammal, said method comprising subcutaneously injecting a composition including a ceramic matrix present in a pharmaceutically acceptable fluid carrier to a tissue site, wherein the ceramic matrix comprises particles having a size distribution in the range from 35 μm to 150 μm .

The claims of the parties which presently correspond to the count are:

Wallace: Claims 1-16.

Hubbard: Claims 21-23, 25-34, 36-37, 39, 41-50.

During the preliminary motion stage of this interference, Hubbard filed, inter alia, a motion to substitute a proposed count A (Hubbard motion 1: Paper No. 31), and a motion to redesignate claims 21-23 and 25-45 as not corresponding to the original count or proposed count A (Hubbard motion 5: Paper No. 35); both motions being opposed by Wallace.

In a decision on motions (Paper No. 57), the Administrative Patent Judge (APJ) agreed with Hubbard that the original count should be broadened. However, rather than substituting the count proposed by Hubbard, the APJ proposed, sua sponte, that the count include in alternative format the independent claims of each party designated as corresponding to the count, namely, Wallace

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claim 1 and Hubbard claims 21 and 46. With respect to Hubbard motion 5, the issue of claim redesignation was deferred to final hearing.

Subsequently, the parties filed a joint stipulation (Paper No. 89) that Hubbard claims 21-23 and 25-45 should be designated as not corresponding to proposed count A. In addition, Wallace withdrew its opposition to Hubbard motions 1 and 5. The stipulation also included a contingent request by Hubbard for entry of adverse judgment.

At the behest of the APJ (Paper No. 90), Hubbard renewed and supplemented the motions in question. Thereupon, the APJ issued a supplemental decision on motions (Paper No. 101) holding, inter alia, that the Hubbard motion to redesignate claims as not corresponding to the count is denied with respect to claims 21-23, 25-34, 36-37, 39, and 41-45, and is granted as to claims 35, 38, and 40. In addition, the APJ redeclared the interference to substitute count 2 (including, in the alternative, the subject matter of Wallace claim 1 and Hubbard claims 21 and 46) for the original count.

The parties then filed another stipulation (Paper No. 111) affirming their agreement that: (1) the count should not include the subject matter of Hubbard claim 21; (2) Hubbard claim 21 and each of the claims depending from it define inventions separately

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patentable from Hubbard claim 46 (and its dependent claims) and Wallace claim 1 (and its dependent claims), viz., should be designated as not corresponding to the count; and (3) Wallace is entitled to an award of priority with respect to a count which embraces only the subject matter of Wallace claim 1 and Hubbard claim 46.

With the foregoing as prologue, the fundamental issue before us for consideration is whether the APJ was correct in holding that the Hubbard motion to redesignate claims as not corresponding to the count should be denied with respect to claims 21-23, 25-34, 36-37, 39, and 41-45.

Hubbard has presented a record (HR-) which includes previously submitted exhibits, filed a brief (HB-) and appeared, through counsel, at final hearing. In view of the agreement between the parties as to the disposition of this interference (Paper No. 111), Wallace had no need to file, and did not file, a brief for final hearing.

No issue of interference-in-fact has been raised in this proceeding.

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Opinion

Of all the Hubbard claims in dispute, claim 21 is the sole independent claim. Accordingly, we shall focus our remarks upon that claim.³

Upon reevaluating the entire record in light of the position taken by Hubbard in his brief, we agree with Hubbard that claim 21, and all the claims which depend on it, define a separate patentable invention within the context of 37 CFR § 1.601(n) from all the other claims of both parties corresponding to the count. Accordingly, this interference is being redeclared to indicate that, of the pending Hubbard claims, only claims 46-50 correspond to the count while claims 21-23, 25-34, 36-37, 39 and 41-45 are redesignated as not corresponding to the count. Consistent with this view, the count is being reformulated to exclude the subject matter of Hubbard claim 21.

Specifically, we agree with Hubbard that the prior art references relied upon by the APJ in the supplemental decision on motions (Paper No. 101), taken in combination with Wallace claims 1-16 and Hubbard claims 46-50 (the parties' involved claims which

³We find it unnecessary to reproduce claim 21 at this point in our decision inasmuch as it appears earlier in our decision as part "(b)" of count 2.

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are not in dispute) are insufficient to establish a prima facie case of obviousness under 35 U.S.C. § 103 as to the subject matter of Hubbard claim 21.⁴

Before individually addressing the prior art references in question, we first focus upon some of the terminology used in claim 21 as that terminology is defined by Hubbard.

Initially, we note that claim 21 requires that the ceramic particles which are used as a component of the soft tissue augmentation material must be both "rounded" and "substantially spherical." These terms are defined in Hubbard's specification (page 9, l. 28-page 10, l. 3) as follows:

The term "substantially spherical" refers to the fact that while some of the present particles may be spheres, most of the particles of the present invention are sphere-like in their shape, i.e., they are spheroidal. FIGURE 1 is illustrative of these spheroidal or substantially spherical characteristics. The terms "rounded" or "smooth, rounded" as used herein refers to the fact even though the present particles are not perfect spheres, they do not have any sharp or angular edges.

According to Hubbard (HB-12), this means that, to be "substantially spherical," the majority of the particles must be spheroidal. We find this interpretation to be reasonably

⁴Because we hold that a prima facie case of obviousness has not been established, we find it unnecessary to discuss evidence adduced by Hubbard to establish unexpected results, namely, the data presented in the first Devine Declaration (HR 71-82).

consistent with the above-cited passage from the Hubbard disclosure and, therefore, find that those of ordinary skill in the art would accept it as an appropriate definition of the term "substantially spherical" when read in light of the specification.

Claim 21 also requires that the ceramic particles be "substantially non-resorbable." This term is defined in Hubbard's specification, page 11, ll. 3-6, as stating that "although some dissolution of the augmentation material may take place over time, it is sufficiently slow so as to allow for replacement with growing tissue cells."

With the foregoing in mind, we find that the prior art references relied upon by the APO, either singly or in combination, fail to render the subject matter of claim 21 obvious when taken in conjunction with Wallace claims 1-16 and Hubbard claims 46-50.

The prior art references in question are Wallace Exhibits 4, 7, and 12 (HF-531, 542, 595 respectively), hereafter referred to, respectively, as Milshek (WX-4), Wallace (WA-7) and Drae-text (WX-14).

We note that the APO in Extnote 7 on page 13 of Paper No. 101 indicates that neither prior art reference, Wallace Exhibit 6, is viewed as cumulative and will not be discussed. Accordingly, we shall not discuss this reference in our decision.

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Misiek (WX-4)

There is no question that Misiek discloses the use of "rounded" ceramic (dense hydroxylapatite) particles as a component of soft tissue augmentation material. There is some question though whether the rounded particles actually used in the working examples of Misiek, viz., Calcitite® (HA-2), are in fact also "substantially spherical" as that term has been defined by Hubbard, given that Calcitite® particles are described in an article by Lemons et al. as being spherical in shape.⁶

Hubbard has adduced convincing evidence that Calcitite® is in fact not "substantially spherical" within our accepted definition of that term. In particular, Dr. Misiek, a co-author of Misiek (WX-4), has testified from personal knowledge that Calcitite® particles are irregularly-shaped with rounded edges and not "substantially spherical" as defined in Hubbard's involved application (HR 600-601). Dr. Misiek postulated that when Lemons et al. described Calcitite® as spherical, they used the term loosely to describe particles having rounded edges. The declarations of Dr. Kent (HR 130-131), Dr. Poser (HR 135-136) and Dr. Hubbard (HR 141-142) are to the same effect. Based on a detailed analysis of the Calcitite® (HA-2) particles shown in

⁶Lemons et al. is cited in footnote 9 on page 15 of Paper No. 101.

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Figure 2 of Misiek, Dr. Poser concluded that these particles "clearly do not possess the morphology of a sphere and would not teach to a person of ordinary skill the importance of a 'substantially spherical' morphology as required by Hubbard claim 21."

In view of the foregoing, we are convinced that the Calcitite® particles described in the Misiek article are not "substantially spherical" as that term is used in Hubbard claim 21, nor does Misiek provide any motivation to select ceramic particles which are both "rounded" and "substantially spherical."

Wallace (WX-7)

The Wallace reference relates to injectable compositions for soft tissue augmentation which include a particulate biocompatible material and a biocompatible fluid lubricant. Wallace further suggests that the particulate biomaterial can be in the form of rigid spherical particles (col. 2, ll. 42-65).

In our opinion, the Wallace reference is not dispositive on the question of obviousness since it does not refer to ceramic particles, such as calcium hydroxyapatite, nor does it suggest that the particles be "substantially non-resorbable" as required by Hubbard claim 21. In this regard, we note that none of the variety of exemplary biomaterials listed in Wallace (col. 3, ll. 1-11) appear to be ceramic materials.

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Draenert (WX-14)

We entirely agree with Hubbard that Draenert is not an effective reference against the claims in question since Draenert teaches away from using "substantially non-resorbable" particles. Indeed, while Draenert uses particles which are spherical in shape, Draenert requires that they be highly porous and "absorbable in the body" in order to provide "channels into which the bone tissue can grow" (col. 1, ll. 10-20; col. 2, ll. 22-27; col. 3, ll. 17-19). This is in contrast to Hubbard's ceramic matrix particles which are made "substantially non-resorbable" by sintering to provide a scaffold or lattice for soft tissue growth at the augmentation site (Hubbard specification: p. 7, l. 31-p. 8, l. 7). Thus, the absorbable particles of Draenert serve a fundamentally different purpose than the substantially non-resorbable particles of Hubbard. These fundamental differences are more fully explained by Poser (HR 138-139) and Devine (HR 108-111).

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For all of the foregoing reasons and in view of Hubbard's concession of priority to Wallace (Paper No. 111), judgment is rendered as follows:

Judgment

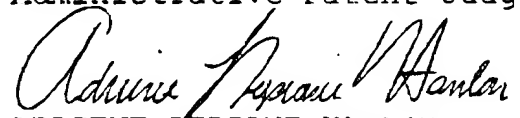
Judgment as to the subject matter of the sole count in issue (count 3)⁷ is hereby awarded to Wallace et al., the junior party.

Accordingly, Hubbard is not entitled to a patent containing claims 46-50 corresponding to the count.

On the record before us in this interference, Wallace et al. are entitled to their patent containing claims 1-16 corresponding to the count.



MARC L. CAROFF
Administrative Patent Judge



ADRIENE LEPIANE HANLON
Administrative Patent Judge



HUBERT C. LORIN
Administrative Patent Judge

BOARD OF PATENT
APPEALS AND
INTERFERENCES

MLC:hh

⁷Count 2 has been replaced by count 3 as the sole count in issue pursuant to the concurrent Redeclaration (Paper No. 123).

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Applicant: Hubbard
Application No. 08/159,071
Filed: November 29, 1993
For: Soft Tissue Augmentation
Material
Accorded Benefit of: U.S.
Application Serial Nos.
07/833,874, filed February 11,
1992, and 07/999,411, filed
January 21, 1993

Redeclaration

In accordance with the concurrent Final Decision in this interference (Paper No. 122), the interference is redeclared as follows:

1. The following count is substituted for count 2:

Count 3.

- (a) [Wallace et al. claim 1]

[1.] A method for augmenting tissue in a living mammal, said method comprising subcutaneously injecting a composition including a ceramic matrix present in a pharmaceutically acceptable fluid carrier to a tissue site, wherein the ceramic matrix comprises particles having a size distribution in the range from 50 μ m to 250 μ m.

or

- (b) [Hubbard claim 46]

[46.] A method for augmenting tissue in a living mammal, said method comprising subcutaneously injecting a composition including a ceramic matrix present in a pharmaceutically acceptable fluid carrier to a tissue site, wherein the ceramic matrix comprises particles having a size

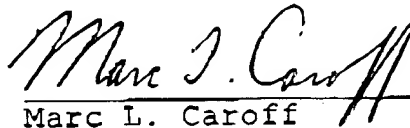
distribution in the range from 35 μm to 150 μm .

2. Hubbard claims 21-23, 25-34, 36-37, 39 and 41-45 are redesignated as not corresponding to the count.

Accordingly, the claims of the parties which correspond to count 3 are:

Wallace et al.: Claims 1-16

Hubbard: Claims 46-50.



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